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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,861

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Yuko Matsumura

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

4148

NOTIFICATION DATE

DELIVERY MODE

03/20/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,861	<b>Applicant(s)</b> MATSUMURA ET AL.	
	<b>Examiner</b> JULIE A. SZPIRA	<b>Art Unit</b> 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/2004 11/14/2007</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2, 4-7 and 13-17** are rejected under 35 U.S.C. 102(b) as being anticipated by **Lipkover (US 5,421,816)**.

**Regarding claim 1**, Lipkover discloses an ultrasonic percutaneous (transdermal) penetration device, comprising: an irradiation (stimuli transducer) unit that applies ultrasonic waves (column 4, lines 62-64) having a frequency of not less than 0.5 MHz (column 5, lines 24-26) to skin (column 4, lines 65-67); and a control unit (column 4, lines 68-68; column 5, lines 1-2) that controls irradiation conditions of the irradiation unit.

The claim limitation “or a surface capable of contacting the medicine” is not given patentable weight as it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

The claim limitation “which, upon allowing a medicine containing an active ingredient to penetrate an organism from a skin surface, allows vibration of ultrasonic waves to penetrate the organism from the skin surface,” is a recitation of intended use, and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from

a prior art apparatus satisfying the claimed structural limitations, and this limitation is not given patentable weight.

**Regarding claim 2**, Lipkover discloses the control unit controlling the frequency, period between on and off of power and irradiation time (column 5, lines 22-27), which are irradiation conditions of ultrasonic waves.

**Regarding claim 4**, Lipkover discloses wherein the irradiation unit applies not less than two ultrasonic waves (stimulus wave, 5KHz-1MHz and pumping pulses, 50 MHz-300MHz) having different frequencies (column 5, lines 23-32).

**Regarding claim 5**, Lipkover discloses the irradiation unit applies an ultrasonic wave having a frequency of virtually 1 MHz (column 5, lines 24-25) and an ultrasonic wave having a frequency of not less than 2 MHz (column 5, lines 30-32).

**Regarding claim 6**, Lipkover discloses a device further comprising a thermal tool (infrared emitter) for warming a portion to be subjected to penetration of the medicine and a photo stimulator (laser emitter) that applies photic stimulation to the portion to be subjected to penetration of the medicine (column 5, lines 40-48).

**Regarding claim 7**, Lipkover discloses an ultrasonic percutaneous (transdermal) penetration device, comprising: a medicine (pharmaceutical agent) containing an active ingredient (column 4, lines 55-56) an irradiation (stimuli transducer) unit that applies ultrasonic waves (column 4, lines 62-64) having a frequency of not less than 0.5 MHz (column 5, lines 24-26) to skin (column 4, lines 65-67); and a control unit (column 4, lines 68-68; column 5, lines 1-2) that controls irradiation conditions of the irradiation unit.

The claim limitation “or a surface capable of contacting the medicine” is not given patentable weight as it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

The claim limitation “which, upon allowing a medicine containing an active ingredient to penetrate an organism from a skin surface, allows vibration of ultrasonic waves to penetrate the organism from the skin surface,” is a recitation of intended use, and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations, and this limitation is not given patentable weight.

**Regarding claim 13**, Lipkover discloses the medicine is impregnated into a base material (column 4, lines 58-60).

**Regarding claim 14**, Lipkover discloses the method comprising the step of simultaneously as a medicine containing an active ingredient is made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through the medicine (column 9, lines 47-55).

**Regarding claim 15**, Lipkover discloses the method comprising the step of after a medicine containing an active ingredient has been made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through a medium that transmits ultrasonic waves (column 6, lines 27-33). Lipkover discloses the first ultrasonic waves stimulating the skin, then the medicine being

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applied, and then pulses of ultrasonic waves being applied that "pump" the medicine through the skin, which is a medium that transmits ultrasonic waves.

**Regarding claim 16**, Lipkover discloses the method comprising the step of after having applied ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface, a medicine containing an active ingredient is made in contact with the skin to which the ultrasonic waves have penetrated (column 6, lines 27-33).

**Regarding claim 17**, Lipkover discloses the method comprising the steps of the following two processes: a process in which ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface (column 6, lines 27-33); and a process in which, simultaneously as the medicine containing an active ingredient is made in contact with the skin, ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface through the medicine (column 9, lines 47-55), and carrying out the selected processes time-serially in succession.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Rowe et al. (US 6,234,990 B1)**.

**Regarding claim 3**, Lipkover discloses the invention substantially as stated above, but fails to disclose a detection unit that detects the depth of a portion for penetration of the medicine, wherein the control unit controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit.

However, Rowe et al. teaches a detection unit (sensor) that detects the depth of a portion for penetration of the medicine, wherein the control unit (controller, 90) controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit (column 12, lines 1-5 and 9-16).

It would have been obvious to one having ordinary skill in the art at the time in the invention was made to provide a depth sensor on the device to allow the medicine to penetrate to the correct depth (column 12, lines 10-12)

6. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Kost et al. (US 4,767,402)**.

**Regarding claim 8**, Lipkover discloses the invention substantially as stated above, but fails to disclose the frequency of the ultrasonic waves in the range of 3 to 7 MHz.

However, Kost et al. teaches a transdermal drug delivery device with ultrasonic enhancement that operates in the range of 20 kHz (.02 MHz) and 10 MHz to enhance the transdermal transfer (column 4, lines 28-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the range between 3 and 7 MHz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Kost et al. (US 4,767,402)** as applied to claim 8 above, further in view of **Hidaka et al (US 4,990,340)**.

**Regarding claim 9**, Lipkover in view of Kost et al. discloses the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) glutathione (column 6, lines 62-63; column 9, line 28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use glutathione as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

8. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Hidaka et al (US 4,990,340)**.

**Regarding claim 10**, Lipkover discloses the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of vitamin A, vitamin A acid derivatives, retinol, glutathione,  $\alpha$ -hydroxy acid and a cell activation agent.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) vitamin A (column 6, lines 62-63; column 9, line 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use vitamin A as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 11**, Lipkover discloses the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of vitamin B group, capsaicin and caffeine.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) capsaicin (column 6, lines 62-63; column 7, line 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use capsaicin as the medicine as it has been proven to have the

ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 12**, Lipkover discloses the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of a thiocarbamate-based agent, an imidazole-based agent, an allylamine-based agent, an amorolfine-based agent, an undecylenic acid and derivatives thereof, an antifungal agent and an antitrichophyton agent.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) an antifungal agent (column 6, lines 62-63; column 8, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an antifungal agent as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rowe (**US 6,234,990 B1**), Ohmachi (**US 7,090,869 B2**), Tachibana (**EP 0 634 189 A2**).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie A. Szpira whose telephone number is (571)270-3866. The examiner can normally be reached on Monday-Thursday 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/  
Examiner, Art Unit 4148

***/Terrell L McKinnon/***

***Supervisory Patent Examiner, Art Unit 4148***